UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

SCOTT R. KROEPLIEN,

Plaintiff,

v. Civil Action No. 10-C-0407

STRYKER CORPORATION and
STRYKER SALES CORPORATION

Defendants.

AMENDED COMPLAINT
(Jury Demanded)

Plaintiff, Scott R. Kroeplien ("Mr. Kroeplien" or "Plaintiff"), by and through counsel, complain of Stryker Corporation and Stryker Sales Corporation (collectively "Stryker" or "Defendants"), demand a jury trial, and allege as follows:

JURISDICTION

1. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. § 1332 in that the plaintiff is a citizen and resident of the State of Wisconsin and the defendant corporations are citizens of the State of Michigan, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

2. This Court has personal jurisdiction over Defendants pursuant to Wisconsin Statute § 801.05(3) and/or § 801.05(4) in that Plaintiff's injury occurred in Wisconsin and arose out of an act or omission within Wisconsin by Defendants or that Plaintiff's injury occurred in Wisconsin and arose out of an act or omission outside of this state by

Defendants while Defendants' products, materials or things processed, serviced or manufactured by the defendants were used or consumed within this state in the ordinary course of trade.

3. Venue is properly laid in this district under 28 U.S.C. §§ 1391(a) and (c) because the substantial part of the events or omissions giving rise to the claim occurred in the Eastern District of Wisconsin.

PARTIES

4. Plaintiff, Scott R. Kroeplien, is and was at all relevant times, a citizen and resident of the State of Wisconsin, currently residing at 611 Danube Court, Unit 4, Sheboygan Falls, WI 53085.

5. Defendant, Stryker Corporation, at all times material hereto, was and is a corporation duly organized and existing under the laws of the State of Michigan, with its principal place of business located at 2825 Airview Boulevard, Kalamazoo, MI 49002 and, at all times material hereto, was doing business in the State of Wisconsin.

6. Defendant, Stryker Sales Corporation, at all times material hereto, was and is a corporation duly organized and existing under the laws of the State of Michigan, with its principal place of business located at 2825 Airview Boulevard, Kalamazoo, MI 49002 and, at all times material hereto, was doing business in the State of Wisconsin.

FACTS COMMON TO THE CLAIMS

7. Stryker, or one of its subdivisions, dba's, or alter egos, designed, tested, manufactured, promoted, and supplied, sold, or otherwise provided a product or device referred to as a Pain Pump.

8. The Pain Pump is a medical device designed and intended to deliver, via catheter, a continuous dose of pain medication directly into the operative site immediately following surgery.

9. The Pain Pump is designed and intended to be used with commonly used anesthetics such as lidocaine, marcaine, or sensorcaine with or without epinephrine, in volumes of 250 cc's or more, over the course of two days or more.

10. The continuous injection of such medications at such doses over time directly into or near the shoulder joint can cause serious and permanent damage to the cartilage of the shoulder joint and surrounding tissues, such as chondrolysis, a complete or nearly complete loss of cartilage in the shoulder joint.

11. At all pertinent times described herein, Stryker represented to the public and to health-care professionals that the Pain Pump was a safe and effective product used to alleviate pain.

12. At all pertinent times described herein, Stryker represented to the public and health care professionals that Pain Pumps could appropriately be used in or near the shoulder joint.

13. At all pertinent times described herein, Stryker knew that its Pain Pump was not cleared by the United States Food and Drug Administration ("FDA") for use in the joint space. In fact, Stryker knew that the FDA had repeatedly rejected requests by Pain Pump manufacturers for permission to market these devices for orthopedic use and/or use in the joint space, based on a lack of safety data.

14. At all pertinent times, Stryker knew or should have known that its Pain Pumps, when used with anesthetic medications in the joint space, could be toxic to shoulder joint cartilage. Stryker failed to conduct meaningful studies to determine the toxicity of its Pain Pumps to human cartilage when used with anesthetic medications in the joint space.

15. Stryker actively promoted its Pain Pumps to orthopedic surgeons for orthopedic use and/or use in the joint space, despite the FDA's denial of permission to market the device for these indications.

16. Stryker did not warn Mr. Kroeplien or his surgeon that its Pain Pumps had been denied clearance by the FDA for orthopedic use and/or use in the joint space and that Pain Pumps' safety for such indications had not been established.

17. Stryker did not warn Mr. Kroeplien or his surgeon about the unreasonable risks and dangers of using the Pain Pump and anesthetic medications in this manner.

18. Mr. Kroeplien's surgeon used the Pain Pump in the manner instructed and directed by Stryker.

19. On or about May 14, 2007, Mr. Kroeplien underwent arthroscopic surgery on his right shoulder in Sheboygan, Wisconsin. This surgery was performed by Dr. Douglas A. Fehrman.

20. During his May 14, 2007 surgery, Dr. Fehrman identified Mr. Kroeplien had a right shoulder labral tear and osteocartilaginous loose body in the shoulder .

21. At the conclusion of the May 14, 2007 surgery, the catheter of a Stryker Pain Pump (REF: 500, PN 500-120 or PN 500-008) was inserted into Mr. Kroeplien's right

shoulder. The Pain Pump was loaded with 0.25% Marcaine with epinephrine with a flow rate of 2.08 ml/hour.

22. Subsequently, on or about December 3, 2007, Mr. Kroeplien underwent arthroscopic surgery on his right shoulder in Sheboygan, Wisconsin. This surgery was also performed by Dr. Douglas A. Fehrman.

23. During his December 3, 2007 surgery, Dr. Fehrman identified rotator cuff tendinitis/impingement syndrome, posterior labral tear, significant glenohumeral chondral thinning/sloughing, and multiple loose bodies associated with Mr. Kroeplien's right shoulder.

24. At the conclusion of the December 3, 2007 surgery, the catheter of a Stryker Pain Pump (REF: 500, PN 500-120 or PN 500-008) was inserted into Mr. Kroeplien's right shoulder. The Pain Pump was loaded with 0.5% Marcaine with epinephrine with a flow rate of 2.08 ml/hour.

25. Stryker made the Pain Pumps available to Mr. Kroeplien and his surgeon for use in Mr. Kroeplien's right shoulder following both surgeries. Additionally, Stryker represented to Mr. Kroeplien's surgeon the Pain Pumps could be used in the way in which they were applied to Mr. Kroeplien.

26. Following the surgeries, Mr. Kroeplien began suffering, and continues to suffer, severe cartilage loss in his right shoulder.

27. Mr. Kroeplien diligently investigated the possible causes of the cartilage loss in his right shoulder by, among other things, repeatedly consulting with health care

professionals. Mr. Kroeplien did not discover until approximately November 2009, that the Pain Pump was the likely cause of the cartilage degeneration in his right shoulder.

a. Following his May 14, 2007 surgery, Mr. Kroeplien attended regular follow up appointments of his right shoulder wherein Dr. Fehrman identified degenerative changes in the glenohumeral joint. Dr. Fehrman never raised the Pain Pump as a possible cause.

b. Following his December 3, 2007 surgery, Dr. Fehrman identified that Mr. Kroeplien continued to have stiffness and pain, and significant degenerative changes at the glenohumeral joint with joint space loss, articular surface irregularity and subchondral cyst formation in both the humeral head and glenoid. Dr. Fehrman never raised the Pain Pump as a possible cause.

c. After undergoing surgery in 2007, Mr. Kroeplien has had regular follow up appointments with Dr. Fehrman. Dr. Fehrman never raised the Pain Pump as a possible cause.

28. The Pain Pump used immediately after Mr. Kroeplien's surgeries caused the degeneration of the cartilage in his right shoulder.

29. The administration of anesthetic solution by the Pain Pump directly led to cartilage and tissue damage in Mr. Kroeplien's right shoulder, resulting in severe pain, weakness, and decreased range of motion in his right shoulder, and requiring further medical treatment, including subsequent surgeries.

30. Mr. Kroeplien's injuries have resulted in permanent disability in his right shoulder and limited daily activity.

31. As a direct result of the use of the Pain Pumps in Mr. Kroeplien's right shoulder, he has suffered harms and losses, including, but not limited to, severe physical pain, mental suffering, inconvenience, loss of the enjoyment of life, past and future medical, surgical, and related expenses, past loss of wages, loss of earning capacity, loss of household services, and care gratuitously rendered.

FIRST CAUSE OF ACTION
(Strict Products Liability)

32. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

33. On information and belief, Defendants designed, tested, manufactured, assembled, labeled, marketed, distributed, and sold Pain Pump(s).

34. The Pain Pump was defectively designed in that, among other things, the continuous infusion of post-surgical anesthetic solution at the delivery rates achieved by the Pain Pump can cause permanent shoulder injury, such as severe chondrolysis and total destruction of cartilage and surrounding tissue.

35. Additionally, the Pain Pump was advertised and marketed for use as a post-surgery mechanism to deliver anesthetic solution to the shoulder.

36. As a result of this design defect, Defendants' Pain Pump is unreasonably dangerous.

37. As a result of its design, when used in a manner reasonably foreseeable to Defendants, the Pain Pump failed to perform as safely as an ordinary and reasonable user would expect.

38. Defendants' Pain Pump was more dangerous than an ordinary and reasonable user of the Pain Pump would expect considering the Pain Pump's characteristics, uses that were foreseeable to Defendants, and any instructions or warnings given by Defendants.

39. Plaintiff did not have actual knowledge, training, or experience sufficient to know the danger posed by use of Defendants' Pain Pump in or near the shoulder joint.

40. On information and belief, Mr. Kroeplien's surgeons did not have actual knowledge sufficient to know the danger posed by use of Defendants' Pain Pump in or near the shoulder joint, and Defendants did not give Mr. Kroeplien or his surgeons sufficient warning regarding the danger posed by use of Defendants' Pain Pump in or near the shoulder joint.

41. The design defect in Defendants' Pain Pump was present at the time Defendants manufactured, distributed, and sold the Pain Pump.

42. The Pain Pump was expected to and did reach the ultimate user without substantial change in the condition in which it was sold and distributed.

43. Defendants knew, or reasonably should have known, of the danger posed by use of its Pain Pump in or near the shoulder joint.

44. Defendants were required to warn about the danger posed by the foreseeable use of its Pain Pump in or near the shoulder joint.

45. Defendants failed to provide an adequate warning to Mr. Kroeplien or his surgeons at the time Defendants' Pain Pump was manufactured, distributed, and sold in that, in light of the ordinary knowledge common to members of the community who use Defendants' Pain Pump, Stryker failed to:

a. Make a warning that was designed to reasonably catch the attention of Mr. Kroeplien or his surgeons;

b. Make a warning that was understandable to Mr. Kroeplien or his surgeons;

c. Make a warning that fairly indicated the danger from the Pain Pump's foreseeable use in or near the shoulder joint;

d. Make a warning that was sufficiently conspicuous to match the magnitude of the danger posed by use of the Pain Pump in or near the shoulder joint;

e. Make a warning that disclosed that the effectiveness of the device was uncertain for use in the shoulder joint space;

f. Make a warning that disclosed that the FDA had considered Pain Pump manufacturers' requests to put this indication in the Pain Pump label and then had rejected this precise indication for the use of Pain Pumps to deliver the pain medicine directly into the joint space; and

g. Make a warning that when used as designed, the Pain Pump delivered, over time, dangerously high doses of medication directly into the shoulder joint.

46. The Pain Pump device was unreasonably and dangerously defective because, at no time did Stryker conduct adequate testing to determine whether Pain Pumps placed for infusion in the joint space, could cause damage to articular cartilage.

47. Defendants' failure to make an adequate warning made Defendants' Pain Pump defective and unreasonably dangerous.

48. The defects in the Pain Pump were a substantial factor contributing to Plaintiff's harms and losses.

SECOND CAUSE OF ACTION
(Negligence)

49. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

50. Defendants had a duty to design, manufacture, test, inspect, assemble, label, market, distribute, and sell its Pain Pump so as to eliminate any unreasonable risk of foreseeable injury.

51. At all relevant times, Defendants breached this duty and failed to use reasonable care in designing, manufacturing, testing, inspecting, assembling, labeling, marketing, distributing, and selling its Pain Pump. Defendants' negligence includes, but is not limited to, the following:

a. Defendants failed to conduct a proper assessment and analysis of the design and assembly of the Pain Pump and its individual parts;

b. Defendants failed to properly test and/or inspect the Pain Pump in the environment in which it was to be used to ensure that the Pain Pump would be safely used in a manner and for a purpose for which it was made;

c. Defendants failed to recall the Pain Pump and failed to provide adequate post-marketing warnings and instructions to physicians and medical providers using the Pain Pump;

d. Use of the Pain Pump in the joint space had not been cleared by the FDA, and in fact had been specifically rejected by the FDA;

e. Continuous injection of certain medications, through a catheter, directly into the shoulder joint, for two or more days had not been adequately tested for safety or effectiveness; and

f. The risk of chondrolysis and other serious post-operative problems associated with using the Pain Pumps as designed and instructed outweighed the possible benefits of such use.

52. Defendants' failure to use reasonable care made its Pain Pump unreasonably dangerous.

53. Defendants were required to warn about the danger posed by the foreseeable use of its Pain Pump in or near the shoulder joint.

54. Defendants failed to exercise reasonable care to provide an adequate warning to Mr. Kroeplien or his surgeons regarding use of the Pain Pump in or near the shoulder.

55. Defendants' negligence was a substantial factor contributing to Plaintiffs' harms and losses.

DAMAGES

56. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

57. As a direct result of Defendants' fault set forth generally above, Plaintiff has suffered and will suffer the following damages, in an amount in excess of $75,000, exclusive of interest and costs, to be proven at trial:

a. General damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

b. Past, present, and future damages for the costs of medical, surgical, and rehabilitative treatment and care; and

c. Damages for Plaintiff's past lost wages and loss of earning capacity.

58. In addition, the acts and omissions of Stryker, as set forth above, are the result of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others, including Plaintiff. Consequently, Defendants are liable to Plaintiff for punitive or exemplary damages, in an amount to be subject to proof at trial.

PLAINTIFF HEREBY DEMANDS A JURY TRIAL OF THIS MATTER ON ALL ISSUES SO TRIABLE.

Patrick O. Dunphy

Patrick O. Dunphy
Attorney Bar No. 1016947
CANNON & DUNPHY, S.C.
Attorneys for Plaintiff
595 North Barker Road
P. O. Box 1750
Brookfield, WI 53008-1750
Telephone: (262) 796-3701
Fax: (262) 796-3711
Email: pdunphy@cannon-dunphy.com

Date: 5/14/10

CO-COUNSEL:

Charles H. Thronson
James T. Blanch
John P. Ball
David K. Heinhold
PARSONS BEHLE & LATIMER
One Utah Center
201 South Main Street, Suite 1800
Salt Lake City, UT 84111
Telephone: (801) 532-1234
Fax: (801) 536-6111
Email: dheinhold@parsonsbehle.com
Application for Admission to Practice Forthcoming